

REMARKS

Reconsideration and allowance of the above-referenced application are respectfully requested.

Claim 78 has been amended. No new matter has been added as a result of this amendment. Claims 55, 59, 64 and 71 have been deleted.

Rejection of Claims 52-78 under 35 U.S.C. Section 101

Claims 52-78 are rejected under 35 U.S.C. Section 101 as lacking a specific, substantial or well established utility. The Examiner admits that while the BS274 consensus sequence is found to be present to a greater extent in breast tissue that this is not considered to be a "real world" use for the claimed polynucleotides, kits or methods of using the polynucleotides of the claimed invention. According to the Examiner, "further experimentation would be required to determine whether the elevated presence of the BS274 consensus sequence, whether the presence of altered BS274, or whether the presence of BS274 in an inappropriate body compartment is indicative of breast disease or breast cancer." The Examiner goes on to state that the specification does not provide any teachings as to the function of the protein encoded by BS274. Applicants respectfully traverse this rejection.

As admitted by the Examiner, the specification teaches that the BS274 consensus sequence is found 28 more times in breast than non-breast libraries. As Applicants discussed in their Preliminary Amendment filed on September 17, 2001 and as shown in Exhibit A included with said Preliminary Amendment, BS274 is strongly expressed in both breast tumor

tissue and breast cancer cell line T47D. The evidence provided in Exhibit A illustrated that the upregulation of BS274 in breast tumors.

- however
also upreg
non tumor breast
samples -
as spec
says

The evidence in Exhibit A further demonstrates that BS274 can be used to determine the origin of a tumor in a patient. It is very difficult for clinicians to determine the origin of a tumor that is found in a metastatic site such as in the lung, liver or bone. Tissue-specific markers, such as BS274, are useful in identifying the site of origin of a particular cancer. This is critical so that a clinician can determine the appropriate course of clinical treatment for that cancer. To illustrate the severity of this problem, Applicants herewith enclose an abstract in English (the entire publication is in Spanish) from a paper entitled "Diagnostico y tratamiento de cancer de origen desconocido", *Anales de medicina interna* 17(11):603-608 (November 2000).

have not
demonstrated
that BS274
is overexpressed
in non breast
tumors as a
result of
breast tumor
metastases

→ paper does
not say that
it is well est.
that overexpressed
breast tumor marker
is end of
breast
primary
cancer.

Thereupon, Applicants submit that BS274 possesses a specific, substantial or well-established utility, namely, that BS274 can be used to identify a tumor as coming from a breast, and not from other locations in the body such as the colon, lung or ovary. Such information is invaluable to a clinician developing a course of clinical treatment for a patient suffering from cancer that originated from the breast. Thereupon, in view of the aforementioned arguments, Applicants submit that this rejection should be withdrawn.

Rejection of Claims 52-78 Under 35 U.S.C. Section 112, First Paragraph

Claims 52-78 are rejected under 35 U.S.C. Section 112, first paragraph. Specifically, the Examiner states that

since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons stated above in the utility rejection, that one skilled in the art clearly would not know how to use the claimed invention. Applicants respectfully traverse this rejection.

Applicants herewith incorporate by reference their arguments made above with respect to the utility rejection. Thereupon, in view of the aforementioned arguments, Applicants submit that this rejection should be withdrawn.

ok

Rejection of Claims 55, 59 and 64 Under 35 U.S.C. Section 112, First Paragraph

Claims 55, 59 and 64 are rejected under 35 U.S.C. Section 112, first paragraph. In view of the deletion of these claims, Applicants submit that this rejection is now moot and should be withdrawn.

Rejection of Claims 52-78 Under 35 U.S.C. Section 112, First Paragraph

- talk to examiner

The Examiner rejected claims 52-78 under 35 U.S.C. Section 112, first paragraph, as containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection.

With respect to independent claims 52, 56, 60, 65, 67, 76, 77 and 78 which contain references to SEQ ID NOS:1-7, Applicants respectfully direct the Examiner's attention to page 13, lines 24-37 through page 14, lines 1-5 and pages

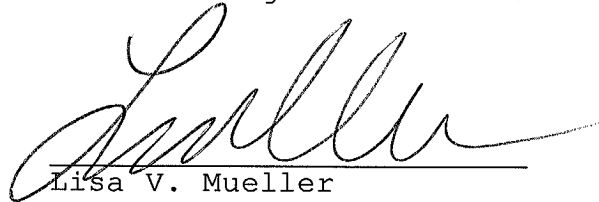
22-24 of the specification. Applicants submit that these portions of the specification provide an adequate written description of the sequences that are encompassed by the claims of the present invention. For example, page 14 of the specification describes several well-known computer programs that can be used to identify sequences encompassed by the claims of the present invention. Use of these computer programs is well known to those skilled in the art. Also, pages 23-24 of the specification describe how sequences can be identified using various hybridization conditions (such as moderately stringent or stringent hybridization conditions). Again, these techniques are routine to those skilled in the art.

With respect to the Examiner rejections in connections with claims 55, 59, 64 and 71, these claims have been deleted. With respect to the Examiner's rejection regarding claim 78 in connection with the "encoding at least one epitope", this claim has been amended.

In view of the aforementioned arguments and amendments, Applicants submit that this rejection should be withdrawn.

Applicants submit that the claims are in condition for allowance. Should the Examiner have any questions concerning the undersigned at the telephone number listed below. If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 23-0785.

Respectfully submitted,
P.A. Billing-Medel et al.

A handwritten signature in dark ink, appearing to read 'Lisa V. Mueller', is written over a horizontal line.

Lisa V. Mueller
Reg. No. 38,978

Wood, Phillips, Katz, Clark & Mortimer
500 West Madison Street
Suite 3800
Chicago, IL 60661
(312)-876-1800 (Phone)



[Diagnosis and treatment of cancer of unknown origin]

[Article in Spanish]

Vazquez Rivera F, Baron Duarte FJ, Lopez Lopez R.

Servicio de Oncologia Medica, Complejo Hospitalario Universitario, Santiago de Compostela, A Coruna.

RECEIVED

JUN 13 2002

TECH CENTER 1600/2900

The carcinoma of unknown primary is a frequent clinical problem and represents a very heterogeneous group of neoplasms. Despite data in the literature indicating minimal success in determining the location of primary carcinomas, these patients continue to be evaluated exhaustively. Clinical treatment is guided by the pathological evaluation of the lesion and is very important the special pathologic techniques characterizing a potentially curable malignancy or patients for whom there is a specific treatment. The majority of the patients are not included in these groups and they should be received treatment in clinical trials.

Publication Types:

- Review
- Review, Tutorial